DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 11 1987

Re: Duromedics Cardiac Valve
Prosthesis
Docket No. 86E-0460

Charles E. Van Horn, Esq.
Director, Patent Examining Group 120
U.S. Patent and Trademark Office
Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the application for patent extension for U.S. Patent 4,328,592 filed by Hemex, Inc. under 35 U.S.C. 156. The medical device claimed by the patent is the Duromedics Cardiac Valve Prosthesis, premarket approval application number P850006.

In the December 9, 1986 issue of the Federal Register, the Food and Drug Administration published its determination of the product's regulatory review period, as required under 35 U.S.C. 156(d)(2)(A). That notice provided that on or before June 7, 1987, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. 156(d)(2)(B)(i) for a determination of whether the patent extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to the notice regarding the Duromedics Cardiac Valve Prosthesis has expired, and FDA has received no such petition. FDA, therefore, considers its determination of the regulatory review period for the Duromedics Cardiac Valve Prosthesis to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson
Director
Health Assessment Policy Staff
Office of Health Affairs

cc: James J. Schumann, Esq.
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